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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------------|---------------------|------------------|
| 10/507,281 | 06/09/2005 | Jean-Christophe Leroux | 1017753-000204 | 4230 |
| 21839 7590 11/06/2008 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404 | | | | |
| EXAMINER SASAN, ARADHANAN | | | | |
| ART UNIT 1615 | | PAPER NUMBER | | |
| NOTIFICATION DATE 11/06/2008 | | DELIVERY MODE ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Advisory Action **Before the Filing of an Appeal Brief**

| | |
|--------------------------------------|--------------------------------------|
| Application No. 10/507,281 | Applicant(s) LEROUX ET AL. |
| Examiner ARADHANA SASAN | Art Unit 1615 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 October 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments have been fully considered but are not persuasive. Applicant argues that Fanara does not teach any organogelling substance which is an amino acid derivative. This is not persuasive because Fanara teaches compositions that have the property of gelling upon contact with mucous membranes (Col. 1, line 65 to Col. 2, line 5) and El-Nokaly teaches n-acyl amino esters as suitable gelling agents (Col. 5, lines 10-14). Applicant argues that Fanara's compositions are not heat sensitive and that Fanara's compositions will not have a transition temperature from liquid to gel lower than the temperature of the site of the injection. This is not persuasive because Fanara teaches compositions that are fluid (Col. 5, lines 18-20) and that a gel forms under the skin or in the muscle (Col. 1, line 65 to Col. 2, line 5). Applicant argues that the elements of the amino acid derivative are not described or even suggested by El-Nokaly. This is not persuasive because El-Nokaly teaches the compatibility of the n-acyl amino acid esters with plant oils, which meets the limitation of an organogelling substance and a hydrophobic organic liquid. When combined with Fanara, the gelling substance of El-Nokaly can be used for in-vivo administration. Fanara's composition is fluid and forms a gel under the skin or in muscle, and allows the sustained release of at least one active substance. Applicant states that the new combination of references is no more appropriate than the previous rejection and was not necessitated by Applicant's amendment. This is not persuasive because Applicant amended claim 1 to include the limitation of "an amino acid derivative" as the organogelling substance. The new ground of rejection in the Office Action of 07/17/08 was necessitated by this amendment; therefore the Office Action was properly made Final.

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615